DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 30, 2014

Alcon Laboratories, Inc.
% Mr. Bob Lundberg
Vice President, VGR, Regulatory Affairs
6201 South Freeway
Fort Worth, TX 76134

Re: K141476
Trade/Device Name: Wavelight FS200
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: OOE
Dated: August 25, 2014
Received: August 29, 2014

Dear Mr. Lundberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K141476

Device Name
Wavelight FS200

Indications for Use *(Describe)*

The WaveLight FS200 Laser System is an ophthalmic surgical laser indicated for use:

• In the creation of a corneal flap in patients undergoing LASIK surgery or other surgery or treatment requiring initial lamellar resection of the cornea.

• In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments.

• In the creation of a lamellar cut/resection of the cornea for lamellar keratoplasty.

• In the creation of a penetrating cut/incision for penetrating keratoplasty and for corneal harvesting.

• In patients undergoing ophthalmic surgery or other treatment requiring arcuate cuts/incisions in the cornea.

• In patients undergoing ophthalmic surgery or other treatment requiring pocket cuts/incisions in the cornea."

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# 5 510(K) SUMMARY

510(k) Summary

This summary document is being prepared in accordance with section 21 CFR 807.92(c).

The submitter of the 510(k) is:

Amy Tezel, PhD
Director, Regulatory Affairs
Alcon Research, Ltd.
6201 South Freeway
Fort Worth, TX 76134
Phone: (817) 568-6189
Fax: (817) 551-4630

Date Summary Prepared: June 3, 2014

Device Subject to this 510(k):

| | |
|---|---|
| Trade Name: | **WaveLight® FS200 Laser System** |
| Common Name: | **Femtosecond Laser** |
| Classification Name: | **Class II**<br>**886.4390 - Ophthalmic laser** |
| Product Code: | **OOE – Ophthalmic Femtosecond Laser** |

## 5.1 Predicate Devices:

The legally marketed device(s) to which we are claiming substantial equivalence are:

| 510(k) Number | Device |
|---|---|
| K131207 | **FEMTO LDV Z6** |
| K113151 | **iFS Laser System** |
| K101006 and K121031 | **WaveLight® FS200 Laser System** |

A side by side comparison of the technology, design principle and mode of operation of the WaveLight® FS200 to the identified predicate devices demonstrates that they are substantially equivalent. All of these devices use laser radiation of similar wavelength and duration (femtosecond pulses) in order to produce a controlled pattern of photo disruption to create cuts/separation in ophthalmic tissue.

The means of fixation of the patient contact portion through sterile and disposable suction rings and patient interfaces is also substantially equivalent to the cleared predicate devices.

Looking at the proposed new indications for use, the arcuate cuts/incisions statement is very similar to the cleared indications for use of all the listed predicate devices; the pocket cuts/incisions statement is very similar to the cleared indications of the main predicate device, the “FEMTO LDV Z6 Femtosecond Surgical Laser”.

Since the initial 510(k) submission (K101006) of the WaveLight® FS200 where substantial equivalence to the Intralase iFS Laser System was demonstrated, the WaveLight® FS200 has been categorized under the same regulation number and product code as the Intralase iFS Laser System (21 CFR 878.4810; GEX).

## 5.2 Device Description:

The WaveLight® FS200 is a stationary scanning-spot femtosecond laser system used to support refractive surgery of the cornea as specified in the indications for use statement.

## 5.3 Indications for Use:

The WaveLight® FS200 Laser System is an ophthalmic surgical laser indicated for use:

- In the creation of a corneal flap in patients undergoing LASIK surgery or other surgery or treatment requiring initial lamellar resection of the cornea.
- In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments.
- In the creation of a lamellar cut/resection of the cornea for lamellar keratoplasty.
- In the creation of a penetrating cut/incision for penetrating keratoplasty and for corneal harvesting.

- In patients undergoing ophthalmic surgery or other treatment requiring arcuate cuts/incisions in the cornea.

- In patients undergoing ophthalmic surgery or other treatment requiring pocket cuts/incisions in the cornea.

## 5.4 Brief Summary of Nonclinical Test and Results:

The WaveLight® FS200 Laser System has undergone testing and is in compliance with the applicable safety standards.

Performance testing on pig eyes addressed the accuracy, precision, and quality of the arcuate corneal cuts/incisions and corneal pocket cuts/incisions produced by the WaveLight® FS200. The results of these tests showed that the achieved performance is consistent with the requirements for these indications.

The comparison with the predicate devices gives evidence that the technology, design principle and mode of operation of the WaveLight® FS200 are fundamentally the same as the cleared predicate devices. All of these devices use laser radiation of similar wavelength and duration (femtosecond pulses) in order to produce a controlled pattern of photo disruption to create cuts/separation in ophthalmic tissue.

The means of fixation of the patient contact portion through sterile and disposable suction rings and patient interfaces is also substantially equivalent to the cleared predicate devices.